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## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 100788.0009P	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US03/17382	International filing date (day/month/year) 28 May 2003 (28.05.2003)	Priority date (day/month/year) 28 May 2002 (28.05.2002)
International Patent Classification (IPC) or national classification and IPC IPC(7): G01N 35/04, 33/543, 35/00; C12Q 1/68; B01L 3/02 and US Cl.: 422/65, 82.01, 68.1, 100; 436/43, 518; 435/5		
Applicant AUTOGENOMICS, INC.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 3 sheets, including this cover sheet.
- ☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 3 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of report with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 15 December 2003 (15.12.2003)	Date of completion of this report 02 September 2004 (02.09.2004)
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 872-9306	Authorized officer <i>Valerie Bell-Harris for</i> MY-CHAU T TRAN Telephone No. 571-272-1600

Form PCT/IPEA/409 (cover sheet)(July 1998)

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US03/17382

## I. Basis of the report

### 1. With regard to the elements of the international application:\*

☐ the international application as originally filed.

☒ the description:

pages 1-17 as originally filed

pages NONE, filed with the demand

pages NONE, filed with the letter of \_\_\_\_\_

☒ the claims:

pages NONE, as originally filed

pages NONE, as amended (together with any statement) under Article 19

pages NONE, filed with the demand

pages 16-18, filed with the letter of 27 July 2004 (27.07.2004)

☒ the drawings:

pages 1-3, as originally filed

pages NONE, filed with the demand

pages NONE, filed with the letter of \_\_\_\_\_

☐ the sequence listing part of the description:

pages NONE, as originally filed

pages NONE, filed with the demand

pages NONE, filed with the letter of \_\_\_\_\_

### 2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

### 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in printed form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

### 4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages NONE

☐ the claims, Nos. NONE

☐ the drawings, sheets/fig NONE

### 5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.  
PCT/US03/17382**V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. STATEMENT**

Novelty (N)	Claims 1-20	YES
	Claims NONE	NO
Inventive Step (IS)	Claims NONE	YES
	Claims 1-20	NO
Industrial Applicability (IA)	Claims 1-20	YES
	Claims NONE	NO

**2. CITATIONS AND EXPLANATIONS**

Claims 1-20 lack an inventive step under PCT Article 33(3) as being obvious over Schubert (US Patent 6,150,173). Schubert discloses a device comprising a pipetting system and a 3D handling system (col. 3, line 47-61). The 3D handling system controls the positioning of the pipettes and dispensing the solution from the pipette (col. 4, lines 21-41). Although the apparatus of Schubert does not expressly include an analytical device comprising two optical energy sources and detectors wherein the first energy source and detector for detecting the volume of the pipette tip and the second energy source and detector is for detecting the surface of a biochip, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to include an analytical device comprising two optical energy sources and detectors wherein the first energy source and detector for detecting the volume of the pipette tip and the second energy source and detector is for detecting the surface of a biochip in the apparatus of Schubert because number of optical energy sources and detectors would be a choice of experimental design and is considered within the purview of the cited prior art.

Claims 1-20 meet the criteria set out in PCT Article 33(2), because the prior art does not teach or fairly suggest an analytic device comprising two optical energy sources and detectors wherein the first energy source and detector for detecting the volume of the pipette tip and the second energy source and detector is for detecting the surface of a biochip.

Claims 1-20 meet the criteria set out in PCT Article 33(4), and thus the presently claimed system has industrial applicability because the subject matter claimed can be made or used in industry.

Applicant amendment to Claims 1, and 11 filed 7/27/2004 is acknowledged, but it is not considered since the amendment was filed after the international preliminary examination report was sent to applicant, i.e. to the written opinion was mailed on 7/1/2004. Applicant response filed 7/27/2004 to the written opinion mailed 7/1/2004 is acknowledged and entered. Applicant alleges that 1) claims 1-20 meet novelty since the reason statement stated that claims 1-20 meet the criteria set out in PCT Article 33(2); 2) the presently amended claims 1-20 is not obvious over the cited reference of Schubert; 3) claims 1-20 is not obvious over the cited reference of Schubert since Schubert does not suggest or taught an alternative energy sources and detectors. It is the examiner position that 1) Claims 1-20 do meet the criteria set out in PCT Article 33(2) as clearly stated in the reason statement and Claims 1-20 were inadvertently place in the wrong box of section (V) with regard to novelty. 2) The presently amended claims 1-20 are not considered since the amendment was filed after the international preliminary examination report was sent to applicant and thus, applicant argument with regard to the amended claims 1-20 is moot. 3) Claims 1-20 is not obvious over the cited reference of Schubert. Schubert disclose a 3D handling system that moves within a 3D working area and has a rotational axis for exactly positioning the pipetting device (col. 4, lines 36-38) and thus would be obvious to add an energy source and detector for detecting the volume of the pipette tip for better monitoring the volume being dispense. The automated device of Schubert also includes an optical measuring system for determining or identifying an analyte in a sample (col. 4, lines 42-49; col. 17-40). Therefore, the presently claimed inventions lack an inventive step under PCT Article 33(3) over the cited reference of Schubert.

NEW CITATIONS

## CLAIMS

What is claimed is:

1. An analytic device having an automatic pipette, comprising:  
a pipette tip receiving element coupled to a mechanism that translates the pipette tip receiving element along at least two of an x-coordinate, a y-coordinate, and a z-coordinate;  
wherein the pipette tip receiving element is further operationally coupled to a sensor that detects presence of a disposable polymer pipette tip that is removably coupled to the pipette tip receiving element;  
a first optical energy source and a first optical energy detector coupled to the pipette tip receiving element wherein the first optical energy source provides a first optical energy to a volume that is enclosed by the pipette tip, and wherein first energy detector receives at least a portion of the first optical energy from the volume;  
a second energy source and a second energy detector coupled to the pipette tip receiving element wherein the second energy source provides a second energy to a surface of a biochip when the pipette tip approaches the surface of the biochip; and  
a processor electronically coupled to the first and second energy detectors, wherein the processor controls accurate aspiration of a predetermined volume using a signal from the first detector, and wherein the processor controls movement of the pipette tip along a z-coordinate using a signal from the second detector.
2. The analytic device of claim 1 wherein the first energy source comprises a laser, and wherein the first energy is provided to the volume via a light guide.
3. The analytic device of claim 2 wherein the accurate aspiration is calculated from a reflected light signal that is detected by the first energy detector.
4. The analytic device of claim 2 wherein the second energy source comprises an ultrasound transducer.
5. The analytic device of claim 1 wherein the sensor comprises an optoelectronic sensor.

AMENDED SHEET

6. The analytic device of claim 1 wherein the disposable pipette tip has a volume of equal or less than 200 microliter.
7. The analytic device of claim 1 wherein the mechanism comprises a robotic arm that translates the pipette tip receiving element along the x-coordinate, the y-coordinate, and the z-coordinate.
8. The analytic device of claim 1 further comprising a data transfer interface.
9. The analytic device of claim 1 wherein the data transfer interface provides data to a person other than the operator, wherein the person is optionally in a remote location relative to the analytic device.
10. The analytic device of claim 1 further comprising a sample station with a multi-well plate and a multi-reagent pack, wherein the pipette tip removes a fluid from at least one of the multi-well plate and the multi-reagent pack and dispenses the fluid onto the surface of the biochip.
11. An automatic pipette that moves along an x, y-, and z-coordinate in an analytic device, the analytic device comprising a disposable pipette tip and a first optical sensor and a second sensor, wherein the first optical sensor detects a volume of a liquid within the pipette tip and wherein the second sensor detects a vertical distance between the pipette tip and a biochip that is disposed in the analytic device.
12. The automatic pipette of claim 11 wherein the pipette tip has a volume of equal or less than 200 microliter.
13. The automatic pipette of claim 11 wherein the first sensor comprises a laser that delivers a laser beam into the pipette tip.
14. The automatic pipette of claim 13 wherein the volume of the liquid is determined using at least one of a destructive interference, a constructive interference, a phase modulation, and a triangulation.
15. The automatic pipette of claim 11 wherein the second sensor comprises an sound transducer that delivers a sound beam to a surface of the biochip.

16. The automatic pipette of claim 15 wherein the vertical distance is determined using a time-of-flight calculation.
17. The automatic pipette of claim 11 wherein first and second sensors are coupled to a robotic arm that moves the pipette along at least one of an x-coordinate, a y-coordinate, and a z-coordinate.
18. The automatic pipette of claim 11 further comprising a third sensor that detects coupling of the disposable pipette tip to the automatic pipette.
19. The automatic pipette of claim 11 further comprising a data transfer interface.
20. The automatic pipette of claim 11 wherein the data transfer interface provides data to a person other than the operator, and wherein the person is optionally in a remote location relative to the analytic device.